

A1

2. (Amended) A pharmaceutical composition as claimed in claim 1, said mixture additionally comprising a pharmaceutically acceptable carrier, which comprises either

A2

(a) particles having a diameter of less than about 10 microns, such that at least 50% of said mixture [the resultant powder] consists of optionally agglomerated primary particles having a diameter of less than about 10 microns; or

(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the said carrier.

A2

4. (Amended) The composition of claim 3, wherein said hormone is vasopressin, a vasopressin polypeptide analogue, desmopressin, glucagon, corticotropin (ACTH), gonadotrop[h]in (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), a somatostatin polypeptide [analogs] analogue, a gonadotropin agonist polypeptide [analogs] analogue (GnRHa), human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

In claim 12, line 3, delete "gycoside" and insert
--glycoside--.

R3

Cancel claims 23-25 without prejudice.

27. (Amended) The method of claim 26 wherein said hormone is vasopressin, a vasopressin polypeptide analogue, desmopressin, glucagon, corticotropin (ACTH), gonadotrop[h]in (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), a somatostatin polypeptide [analogs] analogue, a gonadotropin agonist polypeptide [analogs] analogue (GnRHa), human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

A4 Sub 47

Add new claims 31 and 32.

--31. The composition of claim 1, wherein said enhancer compound is a bile salt.--

--32. The composition of claim 31, wherein said bile salt is sodium taurocholate.--

REMARKS

Applicants have discovered that dry powder formulations which include a biologically active polypeptide and an absorption enhancer are an effective and desirable means for achieving systemic delivery of the polypeptide. A dry powder formulation